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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/610,026	07/03/2000	Todd M. Boyce	285-118	3202

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Peter Dilworth
Dilworth & Barrese LLP
333 Earle Ovington Blvd
Uniondale, NY 11553

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT PAPER NUMBER

3738

DATE MAILED: 12/16/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/610,026

Applicant(s)

BOYCE ET AL.

Examiner

Brian E Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address.--

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION***Drawings***

The new drawings must be made by presenting replacement figures that comply with 37 CFR 1.84. An explanation of the changes made must be presented either in the drawing amendments, or remarks, section of the amendment. If the examiner does not accept the changes to the drawing figure(s), applicant will be notified of any required corrective action in the next Office action. No further drawing submission will be required, unless applicant is notified. The drawings are objected to for introducing new matter into the disclosure. It is not clear that the specification as originally filed supports the figures as presented in the amendment. I.e. what is illustrated in Fig. 6 by the circle? Is Fig. 7 a tube as described in the specification? It does not appear to be what one of ordinary skill in the art would consider as a tube. Other figures that are not necessarily known by the vague description are also unsupported and include Figs. 12-14,16-21,23,24. The positioning of openings or holes, shape variations and dimensions are all critical for different inventions.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDONMENT of the application.

Specification

The disclosure is objected to because of the following informalities: the specification failed to include a Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and *brief description* of the drawing(s) as set forth in 37 CFR 1.74 should be included for the new figures.

Appropriate correction is required.

The amendment filed 9/25/03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the description of the new figures was not descriptive enough before (original specification) to imply that the figures as submitted would necessarily be constructed or designed as presented. Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

Claim 65 is objected to because of the following informalities: line 6 of the claim should include the phrase "or" before the last element recited.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 41-60,61,63-65,67,69-84 are rejected under 35 U.S.C. 102(b) as being anticipated by Dowd et al. (5507813). Dowd et al. disclose the use of bone particles to make a shaped material such as a sheet or plate, col. 2, lines 20-26. Claims in a pending application are given their broadest reasonable interpretation, In re Hyatt, 211 F.3d 54 USPQ2d 1664 (Fed. Cir. 2000). In this instance the recitation "*about* 32%" for a maximum void volume is met by Dowd since the use of "about" is broad and can reasonably be interpreted to include a variance of $\pm 5\%$. Applicant's specification confirms that the subject matter of Dowd's osteoimplant of elongate bone particles in the form of a sheet have a 37% void volume. Thus, it can be fairly said that a variance of (-) 5% results in a void volume of "about" 32%. Dowd also discloses the source of elongate particles can be from cortical, allogenic or xenogenic origin, col. 3, lines 19-22. Regarding claims 57,81-83, the bone particles can be demineralized, col. 3, lines 26-30. The particles can be combined with one or more additives such as plasticizers and binders, col. 1, lines 48-51. Bone powder can also be added in the osteoimplant and can include demineralized bone powder, col. 4, lines 7,45,46. With respect to claims 48,78, the binder can be a polymeric bioabsorbable agent, col. 4, lines 4-6. Regarding claims 45,46,73,75,

Applicant's specification confirms that the subject matter of Dowd's osteoimplant of elongate bone particles has a density "about" 0.8 g/cm^3 .

Claims in a pending application are given their broadest reasonable interpretation, In re Hyatt, 211 F.3d 54 USPQ2d 1664 (Fed. Cir. 2000). In this instance the terminology of *about* (0.8 g/cm^3) for a minimum density is met by Dowd since the use of "about" is broad and the interpretation can reasonably include a variance of $\pm 0.5 \text{ g/cm}^3$. Dowd also discloses the elongate bone particles mechanically adhere to each other by entanglement or adhesives, col. 2, lines 14-17. Dowd additionally discloses the elongate bone particles have at least 60% weight possessing a median length of 2-200mm and width of 1-20mm and also a median length to median thickness ratio of 50:1 up to 500:1, col. 3, lines 1-10. A 3-D architecture can be constructed using a three-dimensional mold, col. 4, line 67. The sheet of material can be formed into a defect shaped plate or membrane (col. 5, lines 27-30) and can be used for arthroplasty, col. 5, lines 41-56. The elongate bone particles can be admixed with one or more biocompatible components such as biostatic/biocidal agents, that include antibiotics, col. 4, lines 1,11,12. Regarding claim 70, Applicant's specification confirms that the subject matter of Dowd's osteoimplant sheet of elongate bone particles has a thickness "about" 2000μ . Claims in a pending application are given their broadest reasonable interpretation, In re Hyatt, 211 F.3d 54 USPQ2d 1664 (Fed. Cir. 2000). In this instance the terminology of *about* (2000μ) for a maximum thickness is met by Dowd since the use of "about" is broad and it can reasonably be interpreted with a variance of $\pm 0.5\text{mm}$.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dowd et al. '813. Dowd is explained supra. However, Dowd does not disclose the bone particles being mixed with a ratio up to 1:4. It would have been an obvious matter of design choice to use a weight ratio up to 1:4 with the osteoimplant of Dowd et al. since applicant has not disclosed that the weight ratios of the bone particles to bone powder as an important feature or solves any stated problem or is established for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the weight ratio of bone powder and bone particles taught by Dowd or the claimed weight ratio up to 1:4 in claim(s) 62 because both the Dowd mixture and the claimed bone powder/bone particle weight ratio up 1:4 perform the same function of reducing the porosity or void volume of the implant and thus its ease of reshaping to the desired structure.

Claims 66,68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dowd et al. '813 in view of Boyce et al. (WO 99/39757). Dowd is explained supra. However, Dowd does not disclose the osteoimplant in laminate form or that there is at least one zone of impermeability to soft tissue ingrowth. Boyce shows an osteoimplant (Fig. 2) having a laminate form. Boyce teaches that the bone elements are crosslinked (pages 15-18) for bonding of the elements. It would have been obvious to one of ordinary skill in the art at the time the

invention was made to use a laminate form as taught by Boyce of the Dowd osteoimplant in order to provide a thicker implant to fill a deeper defect of a patient. Some patient's may have greater bone deterioration than others, thus requiring a laminate form as opposed to a single sheet. It would have been obvious to one of ordinary skill in the art to crosslink the bone elements as taught by Boyce in the osteoimplant of Dowd in order to form a cohesive material. It is inherent that the crosslinked area would prevent soft tissue ingrowth because of the bonds formed.

Response to Arguments

Applicant's arguments filed 9/25/03 have been fully considered but they are not persuasive. The Examiner's interpretation of "about" is not unreasonable, since there was nothing in the specification to provide any indication as to what range of specific activity is covered by the term "about." *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991). The phrase "about" renders the claim broad because the claimed osteoimplant includes a range not actually disclosed (those encompassed by "about") and the scope of the claim is unascertainable. In response to applicant's arguments against the Dowd and Boyce references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicants have also failed to specifically point out the support

in the original disclosure for each of the newly presented claim limitations of claim 49,61,62, (M.P.E.P. 714.02). Thus, because it appears these claims lack criticality it can be said the rejections are proper and claim 62 is obvious to one of ordinary skill in the art.

Conclusion


THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 8:30am to 6pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

TC 3700, AU 3738
Brian E. Pellegrino


Primary Examiner
Paul Prebilic

